

Ethics committees, principles and consequences

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Abstract

When ethics committees evaluate the research proposals submitted to them by biomedical scientists, they can seek guidance from laws and regulations, their own beliefs, values and experiences, and from the theories of philosophers. The starting point of this paper is that philosophers can only be helpful to the members of ethics committees if they take into account in their models both the basic moral intuitions that most of us share and the consequences of people's choices. A moral view which can be labelled as a consequentialist interpretation of mid-level principlism is developed, defended and applied to some real-life and hypothetical research proposals.

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Birgitta Forsman presents the following example at the outset of her pioneering study *Research Ethics in Practice*:

"Just before Christmas 1983, an application was sent to one of the six animal ethics committees in Sweden. The application suggested an experiment on fourteen young pigs, which would be deprived of food for two weeks. Water supply and ventilation would function as usual, but the pig-sty would not be cleaned. The purpose of the experiment was to explore the effects on farming and food supply if there was an accident in a nuclear plant."¹

This is one of the many cases which incurred written protests within the animal ethics committees in Sweden in 1984, and this particular instance triggered a debate which eventually led to changes in legislation. The experiment, however, was performed a few months after the application had been submitted, with the official approval of a three-person animal ethics subcommittee.

My question in this paper is: how should cases like this be assessed from a philosophical viewpoint? Should experiments on animals - or on

humans - be forbidden, if the researchers cannot ask the permission of their subjects? Or should they, on the contrary, be routinely permitted because they can be useful? Or should there be limits which respect the dignity and value of experimental animals, including human beings, as individuals?

It is obvious that fundamental queries like these ought to be answered by the members of ethics committees if they are to make sound decisions concerning research proposals. But can philosophers be of any assistance in this task? My tentative answer is that philosophical models can be helpful only if they are relatively simple and take into account both the consequences of people's choices, and their basic moral intuitions. Therefore I have sketched a view which can perhaps best be labelled as a consequentialist interpretation of the mid-level principlism introduced in the late 1970s by Tom Beauchamp and James Childress and advocated on this side of the Atlantic by Raanan Gillon.

The principles

The point of the doctrine put forward by Beauchamp and Childress is that four principles - the principles of beneficence, non-maleficence, respect for autonomy, and justice - cover most ethical considerations which are relevant to the practice and science of medicine and the provision of health care.^{2,3} A reformulation of these maxims, put in a different order and presented as imperatives, provides the starting point of my analysis:

- (1) Respect the autonomy of persons who are sane, competent and capable of self-determined decision-making!
- (2) Consider the interests of all those affected by the research situation impartially and distribute the benefits and unavoidable harms resulting from the research as fairly as possible!
- (3) Try to avoid inflicting physical or mental harm on sentient beings!
- (4) Aim at restoring and maintaining the physical and mental health of your present and future patients, including your research subjects if they are your patients.

Let me explain briefly what I mean by these principles and how they can be justified in a consequentialist framework.

Autonomy

The principle of autonomy states that if research subjects are capable of self-determined decision-making, then they should be allowed to choose for themselves in which experiments, if any, they will participate. Biomedical professionals have an obligation to explain the options to the candidates, but the choice must in clear cases be left exclusively to the candidates themselves. The justification of this policy has at least two layers. Autonomy can be seen as an independent and intrinsic value which is worth cherishing for its own sake. It can also be seen as an aspect of human wellbeing, in which case its violations can be counted as instances of harm and its enhancement as a positive benefit.⁴

Respect for autonomy is, according to my reading, the only norm needed in situations where individuals are capable of making self-determined choices *and* these choices concern only or mainly the individuals themselves.⁵ The other three principles are, however, required, when it comes to decision-makers who are not at the time of the choice sufficiently autonomous, and in cases where the interests of others are also at stake.

Justice

The principle of justice demands that biomedical professionals treat the interests of all those affected by their decisions impartially. The meaning of this norm can be clarified by dividing individuals into three groups according to the interests they can have. For the purposes of this division I have assumed that beings can have interests only in matters which they can perceive and, in one sense or another, value.

At the top of the list are *autonomous persons* who can have interests in their unrestricted self-determination, in their continued existence, in their health and in the absence of pain, anguish and suffering. The title to self-determination is based on the actual capacity of these individuals to make independent decisions, and the interest to stay alive stems from their awareness of themselves as subjects of mental states, or, as some philosophers prefer to put it, persons.^{6 7} Additionally, these beings can have derived interests in anything that they have chosen of their own free will. *Persons who are not autonomous* can have an interest in their life, health and freedom from unnecessary suffering, and if they are capable of becoming self-determined they can also have an

interest in having this potential fulfilled. At the foot of the ladder are *sentient beings who are not persons*, that is, individuals who can feel pain and pleasure but who are not conscious of themselves as continuous subjects of desires, fears, expectations and other mental states. These sentient beings have an interest in not being subjected to pain, anguish or suffering, and in cases where they will in time become persons, an interest in not having their future interests dwarfed before they have even taken shape.

Although the principle of justice demands that everybody's interests should be considered impartially, it does not require that they should all be catered to with the same intensity. The long term consequences of harming autonomous persons are, in a rationally organized society, almost certainly more considerable than the consequences of harming non-autonomous persons or sentient non-persons. This is why the health of adult human beings who are capable of self-determined decision-making can legitimately and without charges of discrimination take priority over the wellbeing of, say, unborn human beings or some non-human laboratory animals. What the principle does mean, however, is that individuals should not be treated differently purely on the basis of their age, gender, species, skin colour, creed or nationality.

There is no independent justification for the principle of impartiality apart from the indirect proof employed by some egalitarians. The defence states that no excuses are needed for treating individuals equally, and that, on the contrary, the burden of proof lies with those who want to uphold inequalities.

Harms and benefits

Impartiality provides the basis for reckoning the harms and benefits regulated by the principles of non-maleficence and beneficence. It is obvious from any ethical point of view that health care professionals should not unnecessarily harm their patients and clients, but the principle of non-maleficence serves as a useful reminder of the fact that many forms of treatment, and especially experimental treatment, are invasive and potentially dangerous.

The principle of beneficence is in many ways at the core of health care ethics. Every moral person can have a duty to respect other people's autonomy, to consider their interests impartially and to avoid harming them, but it is more questionable whether everybody has an obligation to do good for others. Biomedical professionals do have this duty, at least arguably, because they have, by choosing their careers, undertaken to

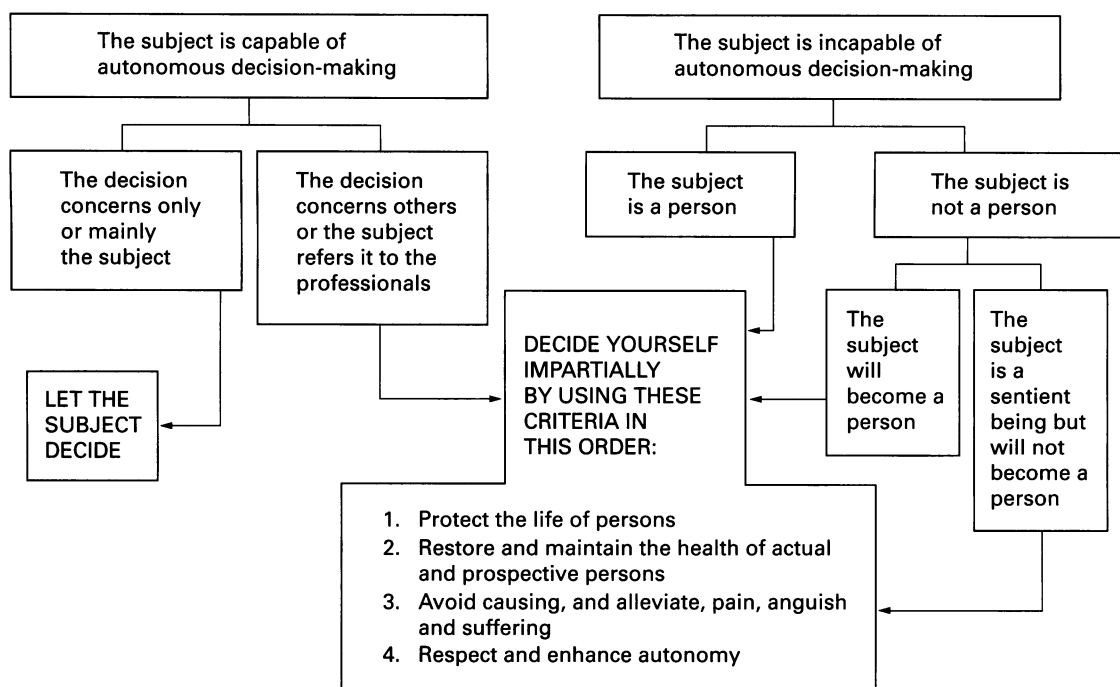


Figure 1: In the figure, the right courses of action can be found by following the lines starting from the general qualities of the potential research subjects, and from the nature of the decisions in question.

help other people, and because it would be a waste of public as well as private resources if they refused to do so in their work.

Consequences and decisions

The ethical view that I have laid out so far in the form of intuitive principles has been summarized schematically in figure 1.

Theoretically speaking, the least complicated cases are the ones that involve the self-regarding choices of autonomous persons. When sane, adult and competent human beings freely make decisions which do not significantly harm others, their choices should be respected absolutely. There are, however, certain practical problems which can complicate the situation. The difficulty that can be assigned specifically to my view is how to identify the decisions which concern only or mainly the agents themselves. My solution is to employ the hierarchically ordered maxims 1-4 that also determine the treatment of non-autonomous persons and prospective persons.

By prospective persons I mean, incidentally, beings who are not persons at the moment, but who will presumably become persons in the future. This category does embrace human embryos and fetuses whom their bearers intend to bring to term, but not those unborn human beings who are destined for abortion. The view presented in the figure should not, then, be interpreted to

prohibit terminations of pregnancy when women autonomously choose this option.

The ranking of the norms 1-4 reflects the facts that, first, being alive is a necessary condition of being healthy, happy and autonomous, and, second, that pain and suffering are often seen as lesser evils than the loss of life or limb. The priorities cannot, however, be absolute - it would not, for instance, be reasonable to prolong an individual's life for a few hours, if by using the same resources the health of hundreds of people could be maintained for decades. These are matters which must be decided case by case, as already suggested by Beauchamp and Childress in their original model.

When it comes to identifying choices which concern only or mainly the decision-makers themselves, the ranking can be used as a rough guideline. Acts and omissions can be called self-regarding in two types of case - and only in them.⁸ First, the conduct of an individual is self-regarding if it does not, directly or indirectly, hurt the interests of others. Second, even if the conduct of an individual does hurt the interests of others, it can be regarded as self-regarding if it is aimed at protecting the individual's own interests which are hierarchically on the same or a more basic level. This means that people cannot be legitimately forced, against their will, to participate in research which is life-threatening, or in

dangerous or painful experiments which are aimed at the enhancement of the health of others, or at their protection against pain.

As regards non-autonomous persons and prospective persons, those who make decisions for them must impartially assess the harms and benefits of the proposed research in terms of life, health, suffering and the enhancement of autonomy. Sentient beings who are not persons have no intrinsic interest in their continued life or health, let alone autonomy, and their treatment should therefore be mainly regulated by the prohibition against causing avoidable pain, anguish and suffering. In a complete evaluation concerning these three categories, and in the cases where the choices are other-regarding, the evils of the research in question must be weighed against the harms and benefits of other action alternatives.

What does lack of autonomy entail?

What, then, does all this mean in terms of ethics committee work? Some answers can be found by analysing the example presented by Birgitta Forsman, with some variations.

In the example, young pigs were about to be deprived of food for a fortnight. One thing most people would agree upon is that since young pigs are not autonomous persons, they cannot be allowed to decide for themselves whether to participate in the experiment or not. While this is probably a sound opinion, a comparison with similar cases involving other kinds of beings demonstrates what it does and does not entail in normative terms.

Consider, for instance, an experiment in which a group of convicted criminals were to be deprived of food for two weeks. Even if the prisoners consented to the programme, their acceptance would not automatically be counted as valid. This is because everyone knows that fasting can be unpleasant, even dangerous, and that nobody forgoes food for fourteen days without a reason. The suspicion that prisoners could cooperate with the scientists against their own better judgment, in exchange for money or institutional privileges, would prevent sensible arbiters from approving their consent, at least without some further consideration.

Another interesting point of comparison is research on young children. Suppose that the application had suggested an experiment in which human infants were to be deprived of food for two weeks. Most of us would presumably find this proposal alarming, but not necessarily for the same reasons. For many, the important factor would be that the infants in question are human.

But if the interests of individuals are considered impartially whatever their species, as I have suggested, then this is not in and by itself decisive. A better alternative within my view would be to argue that the will of the infants, however metaphorical or rudimentary, can be inferred from their behaviour. If they are left unnourished for days, they will cry and display other signs of discomfort and distress, and this can be interpreted as an implicit refusal on their part.

The case of the prisoners indicates that there is a presumption against allowing even consenting individuals to partake in unpleasant research unless it is clear that they have freely chosen to do so. The case of the young children, again, reveals that lack of autonomy offers a point against, rather than in favour of, distressing experiments. Thus the fact that the pigs in the original example were not autonomous persons supports the view that the research should not have been condoned.

The relevance of personhood, sentience and humanity

The question whether fully grown pigs are persons, that is, beings who are aware of themselves as continuous subjects of mental states, is an empirical one, but if they are, then young pigs should be treated as prospective persons. The fact that they are sentient beings can hardly be disputed, and from their status as such it follows that scientists ought to respect their present interests to avoid pain, anguish and suffering. If, in addition, they are prospective persons, it would be wrong to afflict their future lives with distressing memories. In either case, the nature of pigs as living beings provides an argument against the original experiment.

Although the basis for ethical decisions is in my model the same for four categories of beings, this does not mean that there are no differences between them. If autonomous persons refuse to take part in a scientific experiment, this should be counted as a reason against involving them. If the test in question is life-threatening, it can be argued that persons should not be employed. Neither of these considerations can, however, be directly applied to sentient beings who are not persons at the time of the choice. Their interests are, as already noted, limited to the avoidance of present and future pain, anguish and suffering. Of course, all the persons, autonomous or not, whom we know about are also sentient beings, and should be treated accordingly when this is not a threat to their life or autonomy.

Membership in the human species is not, conceptually speaking, a legitimate ground for preferential treatment, but in reality few people

would expose their fellow humans to risks which they see, perhaps correctly, as justified in the case of other animals. There are several reasons for this reluctance, some of them good. Forcing autonomous individuals to participate in unpleasant activities, as well as unnecessarily endangering the lives of human persons, can set a precedent for even more blatant violations of people's need for survival and self-determination. Autonomous persons can also easily compromise the success of the experiments, if they feel that this is called for. And if medical scientists begin to subject children to painful or discomfoting tests without the consent of the parents, this can in the future prevent children from being brought to hospitals and medical centres in the first place. These are all good grounds for employing non-human instead of human subjects in experiments which are too useful not to be performed. But the appeal they make is to the beneficial and harmful consequences of research, not to the intrinsic qualities of acts or biological species.

Harming the subjects to benefit others

In the original example, the utility of the test was so questionable that a full assessment of the long term consequences would have been futile. Depriving young pigs of food for a relatively short period of time can hardly prove anything significant about farming and food supply during a nuclear leak or fallout. As a matter of fact, the information, if any, that was gained by performing the experiment could probably have been found more easily in the literature. The trial was virtually useless and certainly unnecessary, and the distress caused by it was clearly avoidable.

The situation might have been different had the expected outcome of the research been scientifically important and conducive to the improved wellbeing of future pigs or people. The discomfort inflicted on the pigs was not, after all, completely unbearable, and it might have been justified if the trial could conceivably have led to the invention of, say, a cure for cancer. Even in that case, however, the experiment should not have been condoned if the same information could have been reached without involving sentient beings.

It is, no doubt, difficult to make considered judgments regarding painful experiments which can also be beneficial. But a comparison is helpful

here. Given that the benefits promised by animal researchers are realistic and considerable, ethics committee members should think whether or not they would like to condone the same tests on non-consenting prisoners or human infants. If they would, then it is presumably acceptable to use pigs as well. If they would not, they ought to think carefully what the justification for employing pigs but not humans could be. Failure to find a defence for the separation suggests that the proposal should be rejected.

It only remains to be said that my model, like all ethical models, is incomplete. There will always be cases which must ultimately be solved by the use of common sense, shared feelings and compromises. But I hope that the guidelines I have set forth will be of some use in ethics committee work.

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References

- 1 Forsman B. Research ethics in practice: the animal ethics committees in Sweden 1979-1989. *Studies in research ethics* 4. Gothenburg: The Royal Society of Arts and Sciences in Gothenburg, Centre for Research Ethics, 1993: iii.
- 2 Beauchamp T, Childress J. *Principles of biomedical ethics* [4th ed]. New York and Oxford: Oxford University Press, 1994.
- 3 Gillon R, Lloyd A, eds. *Principles of health care ethics*. Chichester: John Wiley & Sons, 1994.
- 4 Häyry H. *The limits of medical paternalism*. London and New York: Routledge, 1991: 44-49.
- 5 See reference 4: 50-77.
- 6 Tooley M. Abortion and infanticide. *Philosophy & Public Affairs* 1972; 2: 37-65: 44.
- 7 Singer P. *Practical ethics*. Cambridge: Cambridge University Press, 1979: 82-3.
- 8 Häyry M. *Liberal utilitarianism and applied ethics*. London and New York: Routledge, 1994: 94-6.